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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,132	11/25/2003	Henry S. Kolesinski	HK002AFP	6350
7590 03/14/2005		EXAMINER		
Gaetano D. Maccarone, Esq.		THERKORN, ERNEST G		
63 Chelsea Street		ART UNIT		
Charlestown, MA 02129		PAPER NUMBER		
		1723		

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/721,132

Applicant(s)

KOLESINSKI ET AL.

Examiner

Ernest G. Therkorn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grandics (U.S. Patent No. 5,466,377). The claims are considered to read on Grandics (U.S. Patent No. 5,466,377). However, if a difference exists between the claims and Grandics (U.S. Patent No. 5,466,377), it would reside in optimizing the steps of Grandics (U.S. Patent No. 5,466,377). It would have been obvious to optimize the steps of Grandics (U.S. Patent No. 5,466,377) to enhance separation.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623). At best, the claims differ from Grandics (U.S. Patent No. 5,466,377) in the clarity of reciting use of a flow channel of 50 microns or greater. Afeyan (U.S. Patent No. 5,605,623) (column 19, lines 40–41) discloses that the diameter of the intraparticle

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flow channels is  $1/3$  of the size of the particle size. It would have been obvious that Grandics (U.S. Patent No. 5,466,377)'s flow channels are 50 microns or greater because Afeyan (U.S. Patent No. 5,605,623) (column 19, lines 40-41) discloses that the diameter of the intraparticle flow channels is  $1/3$  of the size of the particle size.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grandics (U.S. Patent No. 5,466,377) alone or Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623) as applied to claims 1, 2, 4, and 5 above, and further in view of either Novak (U.S. Patent No. 4,155,846) or Chabrol (French Patent No. 2,645,965) including applicants' submitted translation of French Patent No. 2,645,965. At best, the claim differs from Grandics (U.S. Patent No. 5,466,377) alone or Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623) in reciting use of a plurality of capture elements. Novak (U.S. Patent No. 4,155,846) (column 4, lines 40-61) discloses that use of a plurality of segments allows for many benefits including use of decreased elution volumes and higher concentration of desired solute. The paragraph bridging pages 1 and 2 of the translation of Chabrol (French Patent No. 2,645,965) discloses that use of modules allow a chromatographic device to have constant effectiveness whatever volumes are brought into play. It would have been obvious to use a plurality of capture elements in Grandics (U.S. Patent No. 5,466,377) alone or Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623) either because Novak (U.S. Patent No. 4,155,846) (column 4, lines 40-61) discloses that use of a plurality of segments allows for many benefits including use of decreased elution volumes and higher concentration of desired solute

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or because the paragraph bridging pages 1 and 2 of the translation of Chabrol (French Patent No. 2,645,965) discloses that use of modules allow a chromatographic device to have constant effectiveness whatever volumes are brought into play.

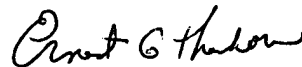
Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grandics (U.S. Patent No. 5,466,377) alone or Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623) as applied to claims 1, 2, 4, and 5 above, and further in view of Pretorius (U.S. Patent No. 3,522,172) and either Koslow (U.S. Patent No. 4,780,113) or Lihme (U.S. Patent Publication No. 2004/0140265) and Allington (U.S. Patent No. 4,966,696). At best, the claim differs from Grandics (U.S. Patent No. 5,466,377) alone or Grandics (U.S. Patent No. 5,466,377) in view of Afeyan (U.S. Patent No. 5,605,623) in reciting use of sintered steel. Pretorius (U.S. Patent No. 3,522,172) (column 1, lines 21-24, column 9, lines 73-74, and column 10, lines 18-28) discloses that metal beads may be sintered and coated in a chromatography column to achieve a favorable relationship between column capacity and flow volume. Each of Koslow (U.S. Patent No. 4,780,113) (column 17, lines 3-12) or Lihme (U.S. Patent Publication No. 2004/0140265) (page 5, paragraph 64) discloses that stainless steel may be coated by adsorbent. Allington (U.S. Patent No. 4,966,696) (column 6, lines 37-40) discloses that stainless steel may be sintered. It would have been obvious to use sintered steel in Grandics (U.S. Patent No. 5,466,377) because Pretorius (U.S. Patent No. 3,522,172) (column 1, lines 21-24, column 9, lines 73-74, and column 10, lines 18-28) discloses that metal beads may be sintered and coated in a chromatography column to achieve a favorable relationship between column capacity

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and flow volume, each of Koslow (U.S. Patent No. 4,780,113) (column 17, lines 3-12) or Lihme (U.S. Patent Publication No. 2004/0140265) (page 5, paragraph 64) discloses that stainless steel may be coated by adsorbent and Allington (U.S. Patent No. 4,966,696) (column 6, lines 37-40) discloses that stainless steel may be sintered.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ernest G. Therkorn**  
**Primary Examiner**  
**Art Unit 1723**

EGT  
March 8, 2005